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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,564	09/04/2001	Nida Abdul-Ghani Nassief		8476

7590 05/12/2004

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EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,564	NASSIEF, NIDA ABDUL-GHANI	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *25-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Response dated February 11, 2004

1. In the Response filed February 11, 2004, claims 1-24 were canceled and claims 25-34 were added.

2. Claims 25-34 are pending.

3. The objection to claims 9-13 and 15-16 under 37 CFR 1.75(c) as being in improper form has been rendered moot in view of applicant's amendment filed February 11, 2004.

4. The rejection of claims 1, 2, 7, 17, 19, 22, and 24 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process results in an improper definition of a process has been rendered moot in view of applicant's amendment filed February 11, 2004.

5. The rejection of claims 1, 5, and 17-24 under 35 U.S.C. 112, first paragraph, has been rendered moot in view of applicant's amendment filed February 11, 2004.

6. The rejection of claims 1-2, 5-8, 14, and 17-24 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of applicant's amendment filed February 11, 2004.

7. The rejection of claims 1-8, 17-19, 22, and 24 under 35 U.S.C. 102(b) as being anticipated by Sanchez Palacios A. et al. Allergol Immunopathos (Madr), **1992**, Vol 20 (1), pages 35-39 (Sanchez) has been rendered moot in view of applicant's amendment filed February 11, 2004.

Election/Restrictions

8. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 25-27, drawn to a pharmaceutical composition consisting essentially of glycophosphopeptical and a method of treatment of allergy and asthma in patients in need of multiple drugs daily comprising administering said glycophosphopeptical composition, classified in class 514, subclass 54.

II. Claims 28-29, 31, and 33, drawn to a pharmaceutical composition consisting essentially of the herbal seeds of *Nigella sativa*, classified in class 424, subclass 725.

III. Claim 30, drawn to a method of treatment of allergy and asthma patients in need of multiple drugs daily comprising administering a pharmaceutical composition consisting essentially of the herbal seeds of *Nigella sativa*, classified in class 424, subclass 810.

IV. Claim 32, drawn to a method of treating Crohn's disease comprising administering a pharmaceutical composition vaccine from *Nigella sativa*, classified in class 424, subclass 725.

V. Claim 34, drawn to a method of treatment of influenza and common cold comprising administering a pharmaceutical composition vaccine from *Nigella sativa*, classified in class 424, subclass 725.

The inventions are distinct, each from the other because of the following reasons:

9. Inventions I and (II, III, IV, or V) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions employ patentably distinct active agents. The active agent of Invention 1 is glycophosphopeptical, a glucomannan from *Candida utillis* while the active agent recited in Inventions II, III, IV, and V is a pharmaceutical composition derived from *Nigella sativa*. No relationship between the active agents employed has been established and, as such, are seen to employ different modes of operation.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, III, IV, or V, restriction for examination purposes as indicated is proper.

10. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II may be employed in the method of Invention IV.

Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group II, restriction for examination purposes as indicated is proper.

11. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II may be employed in the method of Invention V.

Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Group II, restriction for examination purposes as indicated is proper.

12. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II may be employed in the method of Invention III.

Because these inventions are distinct for the reasons given above and the search required for Group V is not required for Group II, restriction for examination purposes as indicated is proper.

13. Inventions III, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to the treatment of

distinct medical conditions. The treatment of any one of the specific recited conditions would not render obvious the other two.

Because these inventions are distinct for the reasons given above and the search required for Group III, IV, or V is not required for the other two Groups, restriction for examination purposes as indicated is proper.

14. Applicant is advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a

matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 10:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

ptl
May 5, 2004

Dr. Samuel Barts
Primary Patent Examiner
Technology Center 1600